



Coseal
Surgical Sealant

DISTRIBUTED BY
ARTIMEDICA

STRONG

WHEN YOU NEED IT.³

GONE

WITHIN 30 DAYS.^{†2}

Postoperative hemostasis
protection in a resorbable
surgical sealant.^{†1,2}

Resorbed within 30 days of application. Remains at
application site for up to 7 days.² [†]Preclinical data.
Results may not correlate to performance in humans.

COSEAL is indicated for use in vascular reconstructions to achieve
adjunctive hemostasis by mechanically sealing areas of leakage.

Please read Important Risk Information on the back cover.

Baxter



STAYS STRONG

WHEN THE PRESSURE'S ON

COSEAL Surgical Sealant is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.¹

COSEAL Surgical Sealant is designed to provide a rapid intraoperative seal at the suture line and to maintain this protection during the critical postoperative period.^{1,2} This allows the body time to complete its natural wound healing process at the anastomosis, supporting the integrity of your work at vascular reconstruction sites that may be at risk for increased bleeding due to:^{1,3-6}

- Coagulopathies
- High pressure suture lines
- Friable vascular tissue

COSEAL Surgical Sealant is not to be used in place of sutures, staples, or mechanical closure. Do not inject **COSEAL** into vessels.



Listed in the Blood Conservation Clinical Guidelines of
The Society of Thoracic Surgeons[®]

Please read Important Risk Information on the back cover.



As a fully synthetic hydrogel, **COSEAL** Surgical Sealant is developed for the right balance of strength, elasticity and time-to-resorption, and is completely free of glutaraldehyde and bovine components.¹

BURST STRENGTH

Can withstand postoperative spikes over 5x normal systolic pressure at up to 660 [\pm 150] mm Hg (in vitro burst test for closure of puncture defects 0.6-0.9 mm diameter, n=4) in porcine carotid artery.^{†3}

ELASTICITY

Thin, motion-responsive seal provides biomechanical compatibility and supports natural vascular dilation.^{†7}

RESORPTION

Resorbed within 30 days of application. Remains at application site for up to 7 days.^{†2}

[†]Preclinical data. Results may not correlate to performance in humans.



COHESIVE

CONTROL & CONFIDENCE

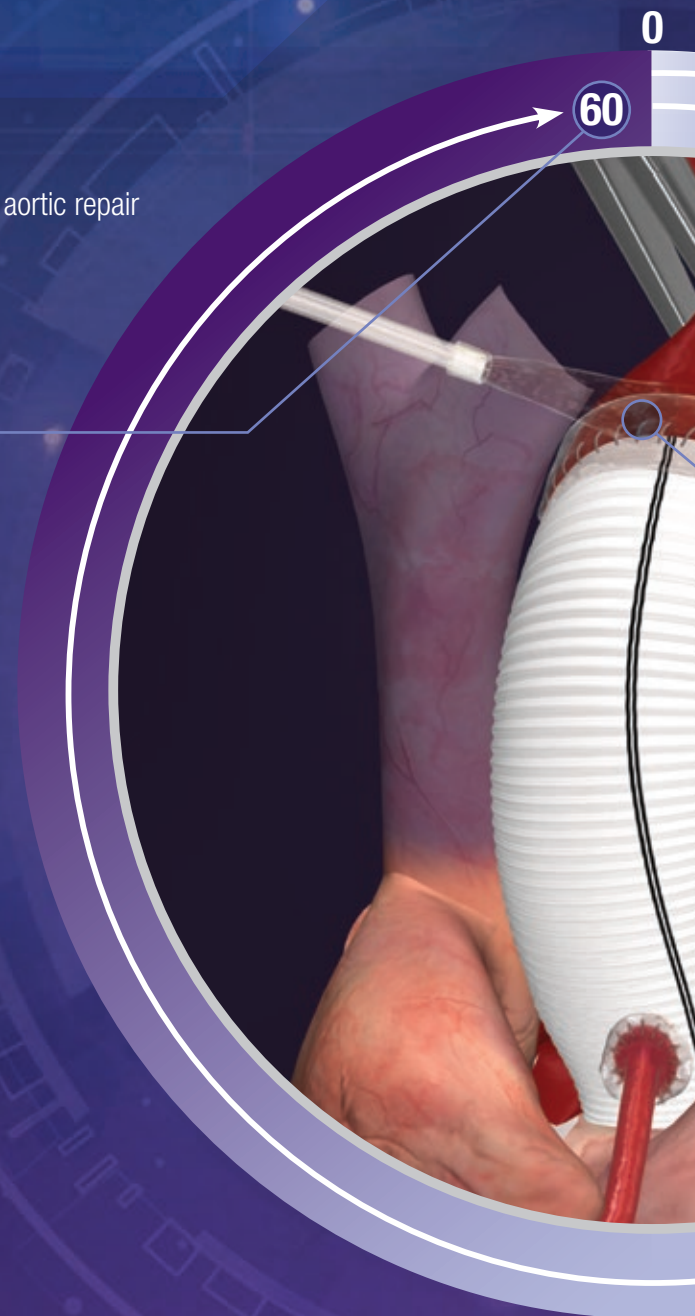
COSEAL Surgical Sealant provides rapid intraoperative control for aortic repair and high-pressure suture lines.^{1,5,6}

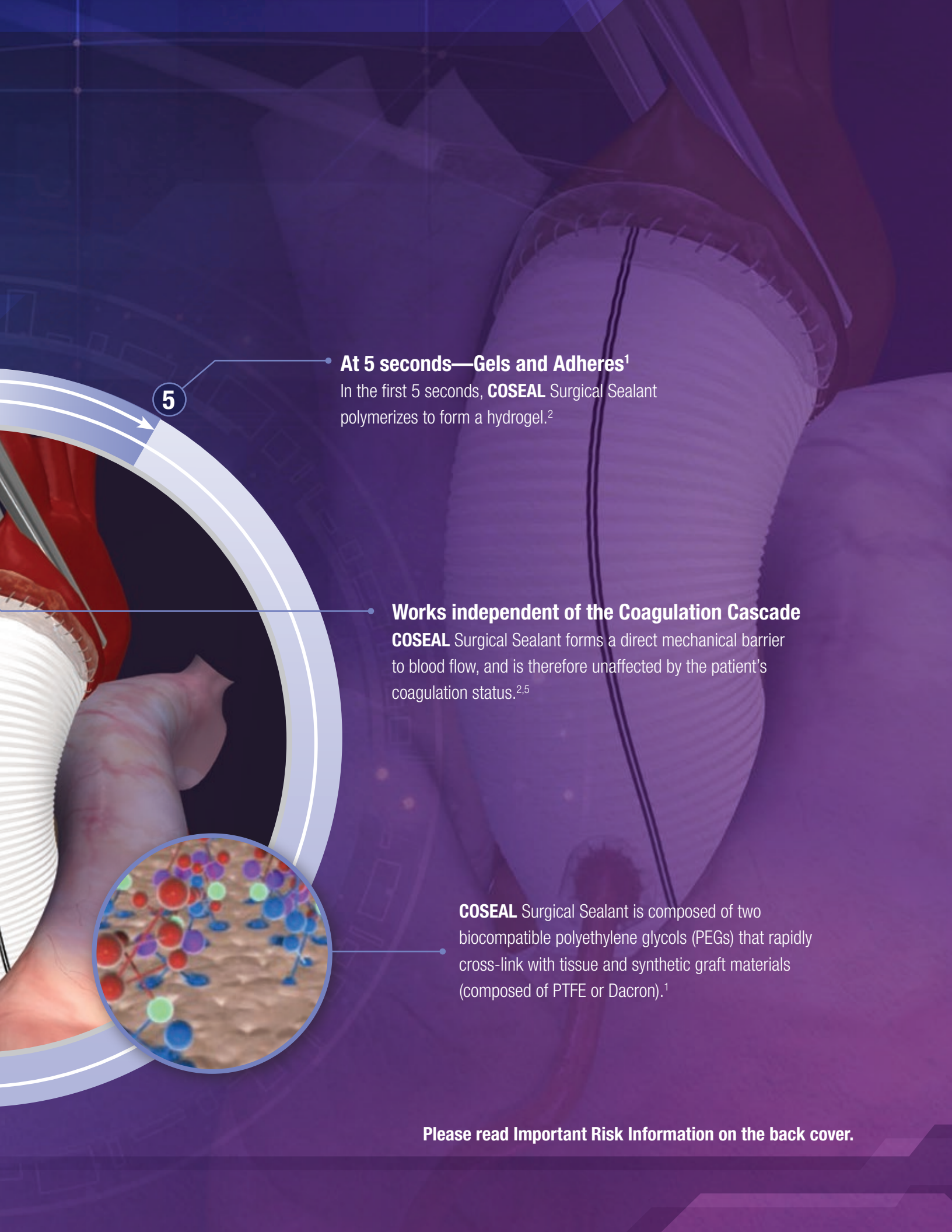
At ~60 seconds—Full Seal Achieved¹

At 1 minute, **COSEAL** Surgical Sealant achieves a full mechanical seal to manage suture hole bleeding.^{1,4,5}

Important Risk Information

- Apply only to dry fields in a thin layer¹
- Wait at least 60 seconds post-application before applying irrigation, contacting the sealant, or restoring circulation and resuming procedure¹
- **COSEAL** Surgical Sealant swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel resorbs¹





5

At 5 seconds—Gels and Adheres¹

In the first 5 seconds, **COSEAL** Surgical Sealant polymerizes to form a hydrogel.²

Works independent of the Coagulation Cascade

COSEAL Surgical Sealant forms a direct mechanical barrier to blood flow, and is therefore unaffected by the patient's coagulation status.^{2,5}

COSEAL Surgical Sealant is composed of two biocompatible polyethylene glycols (PEGs) that rapidly cross-link with tissue and synthetic graft materials (composed of PTFE or Dacron).¹

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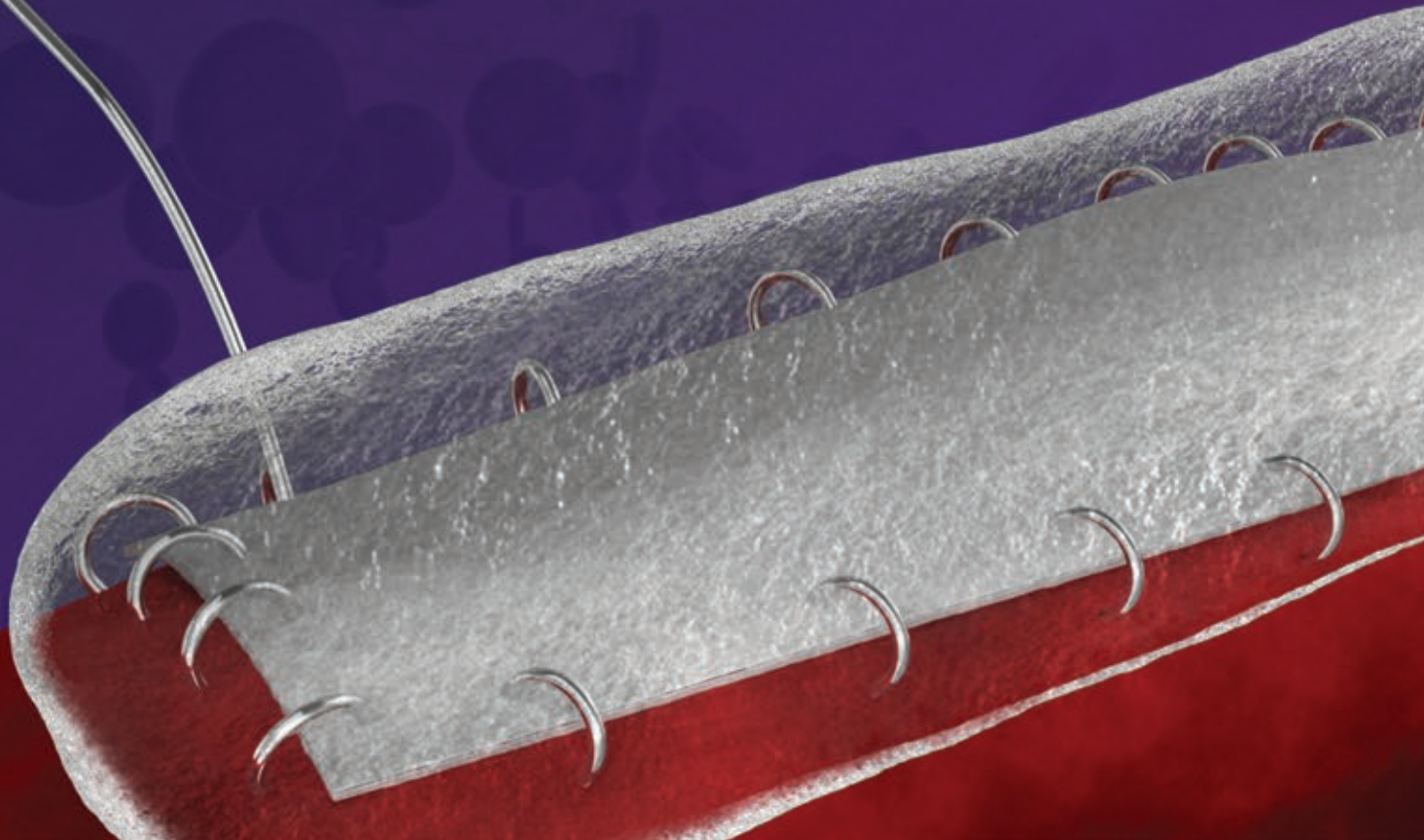


APPLICATION

VERSATILITY THAT'S CLEAR

COSEAL Surgical Sealant is easy to apply how and where you want.

- Translucent seal – Helps to keep suture lines visible
- Can be sutured through - After **COSEAL** Surgical Sealant has polymerized, additional sutures can be easily placed through it without disturbing the seal⁸
- No refrigeration required - **COSEAL** Surgical Sealant can be stored at room temperature (approximately 25 °C)¹
- Multiple application options – **COSEAL** Surgical Sealant may be used with a full range of spray systems for focal and broad application¹
 - Use caution when applying with pressurized gas¹



For broad application

SpraySet with EASYSpray
Pressure Regulator Unit

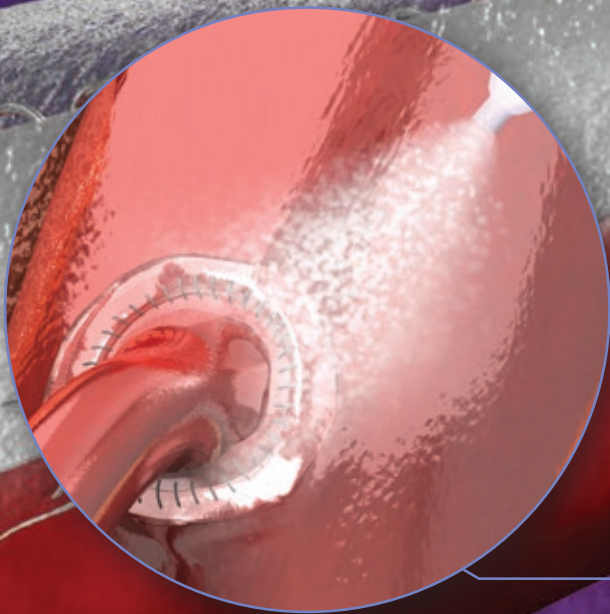


For focal application

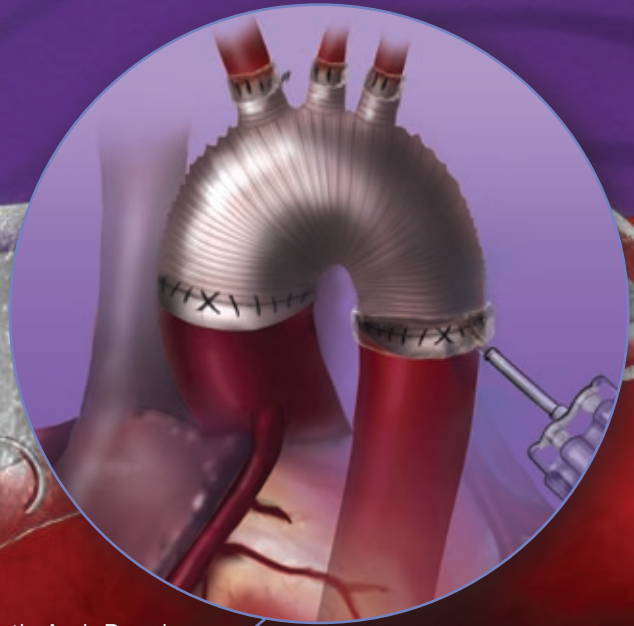
Flex Direct Tips
(7 cm; 22 cm for MIS)



Rx Only. For safe and proper use, refer to complete Instructions for Use.



Distal Coronary Anastomosis



Aortic Arch Repair

Please read Important Risk Information on the back cover.



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COSEAL Surgical Sealant Indication

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

Important Risk Information for COSEAL

- **COSEAL** is not to be used in place of sutures, staples, or mechanical closure.
- **COSEAL** swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel resorbs. Therefore, surgeons should consider the maximum swell volume and its possible effect on surrounding anatomic structures potentially sensitive to compression.
- Apply only as a thin layer.
- Use caution when applying with pressurized gas.
- Do not place devices or other objects on top of tissue where **COSEAL** has been applied, until the material is fully polymerized (non-tacky).
- Do not apply **COSEAL** over any devices or objects that will need to be removed. **COSEAL** must not be used as a mechanism of adherence, even temporarily, for any object.
- Do not inject **COSEAL** into vessels.
- In vivo testing demonstrated a mild skin sensitization response in an animal model. Similar testing in humans has not been conducted.

Rx Only. For safe and proper use of these devices, refer to the appropriate full device Instructions for Use.

References

1. COSEAL Surgical Sealant Instructions for Use, Hayward, CA: Baxter Healthcare Corporation. March 2009. 2. Hill A, Estridge TD, Maroney M, et al. Treatment of suture line bleeding with a novel synthetic surgical sealant in a canine iliac PTFE graft model. *J Biomed.* 2001;58: 308-312. 3. Wallace DG, Cruise GM, Rhee WM, et al. A tissue sealant based on reactive multifunctional polyethylene glycol. *J Biomed.* 2001;58: 545-555. 4. Natour E, Suedkamp M, Dapunt OE. Assessment on the effect of blood loss and transfusion requirements when adding a polyethylene glycol sealant to the anastomotic closure of aortic procedures: a case-control analysis of 102 patients undergoing Bentall procedures. *J Cardiothorac Surg.* 2012;7:105. 5. Hagberg RC, Safi HJ, Sabik J, et al. Improved intraoperative management of anastomotic bleeding during aortic reconstruction: Results of a randomized controlled trial. *Am Surg.* 2004;70: 307-311. 6. Glickman M, Gheissari A, Money S, et al. A polymeric sealant inhibits anastomotic suture hole bleeding more rapidly than Gelfoam/Thrombin. *Arch Surg.* 2002;137: 326-331. 7. Azadani AN, Matthews PB, Ge L, et al. Mechanical properties of surgical glues used in aortic root replacement. *Ann Thorac Surg.* 2009;87(4):1154-1160. 8. DeAnda A, Jr., Elefteriades JA, Hasaniya NW, Lattouf OM, Lazzara RR. Improving outcomes through the use of surgical sealants for anastomotic sealing during cardiovascular surgery. *J Card Surg.* 2009;24(3):325-333. 9. Ferraris VA, Brown JR, Despotis GJ, et al. 2011 Update to The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clinical Practice Guidelines. *Ann Thorac Surg.* 2011;91:944-982.

Reorder Number	Product Information	Quantity
934070	COSEAL Surgical Sealant 2 mL	1 each
934071	COSEAL Surgical Sealant 4 mL	1 each
934072	COSEAL Surgical Sealant 8 mL	1 each
934033	COSEAL Replacement Applicator (7 cm)	case of 5
934034	COSEAL Extended Applicator (22 cm)	case of 10
0600012	EASYSpray Pressure Regulator Unit	1 each
0600021	COSEAL SpraySet (for use with EASYSpray Pressure Regulator Unit)	case of 10

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To order COSEAL Surgical Sealant, call 1-888-229-0001

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